

Exhibit K



Brad Hammock

Email: bhammock@dollartree.com

January 19, 2022

Highly Confidential Business Information

Via Email

Chad J. Whitwell

Compliance Officer

Office Human and Animal Food Operations Division 3 West (TX, OK, AR)

Office of Regulatory Affairs

Chad.Whitwell@fda.hhs.gov

Thank you for the opportunity to respond to your concerns regarding the product distributed from the Family Dollar Distribution Center (DC) located in West Memphis, AR. Family Dollar has performed an evaluation of the potential contamination of products that were shipped from the DC. This evaluation consisted of reviewing:

- Consumer complaints from January 1, 2021 to January 17, 2022, to identify if any complaints were made related to product that looked damaged or unusual by the consumer;
- The percentage of damaged goods received at the stores from this DC; and
- The training of personnel on food safety practices conducive to reducing the chances of shipping potentially adulterated product from this DC.

Based on this review, we believe that Family Dollar's existing processes have sufficiently prevented potentially contaminated, or otherwise adulterated, product from being offered for sale at Family Dollar's retail stores (the Stores). Therefore, we believe that a recall of products shipped from the DC is not warranted at this time. However, we wish to obtain the U.S. Food and Drug Administration's (FDA) input on the results of this review and this preliminary conclusion in order to reach agreement on appropriate next steps.

A review of the consumer complaints found that most cases related to the use of the products did not relate to any damaged packaging or product that looked unusual to the consumer. From a total of 16 complaints received from January 1, 2021 to January 17, 2022, only three were related to food items and none related to drugs or devices. A summary of these complaints can be found in the attached file **DC202 Stores PL Claims as of 1-17-22**.

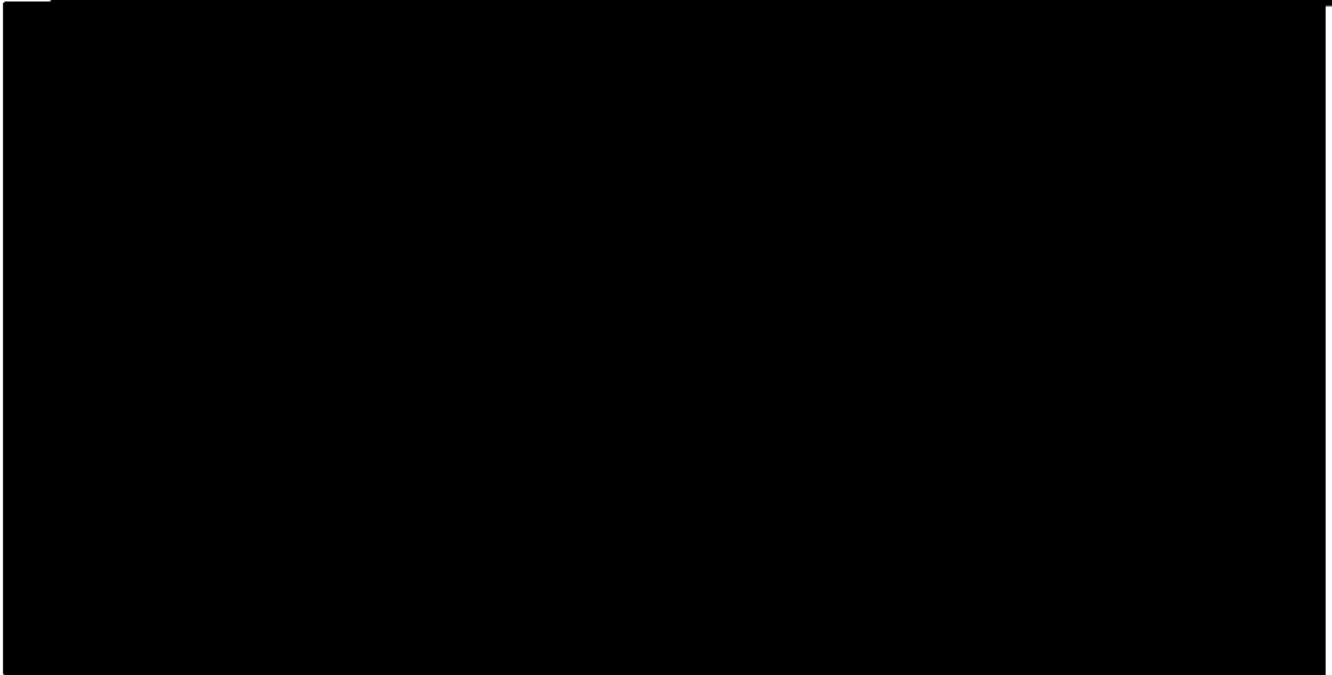
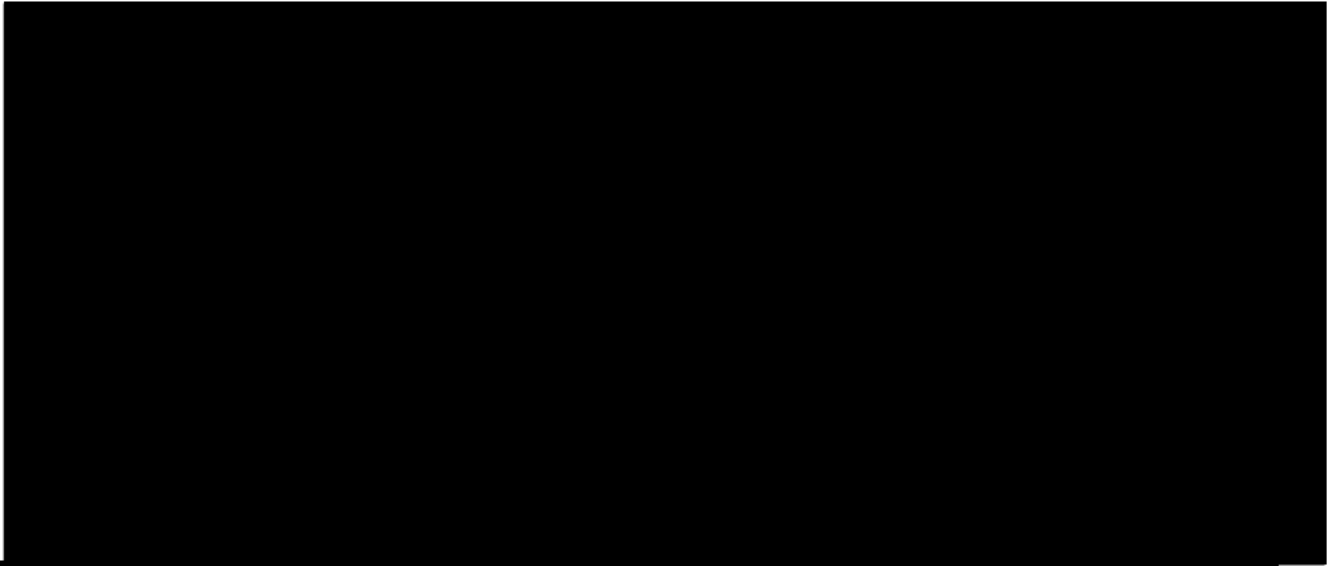
The Stores' processes are outlined on two attached documents for the Company's practices and protocol to remove any damaged product received from the DC before they are placed on the shelves. Store employees are trained to perform a thorough review of the incoming goods off of the trucks as well as when they are shelving the individual items. These damaged goods are separated and disposed of as there is no reverse distribution back to the DC. These documents are as follows:

500 Volvo Parkway, Chesapeake, VA 23320
Main (757) 321-5000 Fax (757) 321-5949



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Further, and specific to the potential for contamination of over-the-counter (OTC) drug and medical device products held in the DC, we believe a recall action would be unwarranted at this time based on available information and the following considerations:



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- Recognizing that OTC drug and device products are, in general, packaged using highly impervious primary packaging components and seals that are designed specifically to safeguard the drug contents within the container from direct exposure to solid, particulate (e.g., dust), liquid, vapor, or other foreign materials contamination, it should be assumed in the absence of direct evidence that the integrity of the primary drug/device packaging has been compromised, that the original manufacturer's primary packaging is adequate to prevent adulteration of the product due to exposure to any potential contaminants presently in question.
- As stated above, we have also not received consumer complaints about OTC drug and device products appearing damaged or unusual to the consumer.

Based on these findings, we believe that the DC's existing processes have sufficiently prevented potentially contaminated, or otherwise adulterated, product from being offered for sale at any of the Stores and that a recall is, therefore, not warranted. Family Dollar is also reviewing all of its Store and DC processes for further improvement. We reiterate, however, that we wish to obtain FDA's input on these findings and this preliminary conclusion to obtain agreement on appropriate next steps.

Sincerely,

Brad Hammock

Brad Hammock
Director Environmental, Safety and Health

Attachments:

- DC202 Stores PL Claims as of 1-17-22
- D100-Program-Best-Practices
- D100-Training-Reference-Guide-2020
- DC-Safety-Training

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